DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 22, 2014

Milliken Healthcare Products, LLC
% Dr. Gordon Macfarlane
Aptiv Solutions Incorporated
62 Forest Street, Suite 300
Marlborough, Massachusetts 01752

Re: K141603
Trade/Device Name: ULTRA Silver Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 3, 2014
Received: October 6, 2014

Dear Dr. Macfarlane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141603

Device Name
ULTRA Silver Dressing

Indications for Use *(Describe)*
The ULTRA Silver Dressings are indicated for management of partial thickness burns, incisions, skin grafts, donor sites, lacerations, abrasions, and Stage I-IV dermal ulcers (vascular, venous, pressure, and diabetic).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

ULTRA SILVER DRESSINGS
510(K) SUMMARY

(per 21CFR 807.92 and http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm)

1. SPONSOR/MANUFACTURER

Milliken Healthcare Products, LLC
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Spartanburg, SC 29303

Contact Person: Brian J. Lindsay
Telephone: 864-503-1323

Date Prepared: 26 August 2014

Consultant/Contact:
Aptiv Solutions
62 Forest Street, Suite 300
Marlborough, MA 01752

Primary Contact: Gordon MacFarlane, PhD, RAC
Telephone: 919-873-8962

2. DEVICE NAME

Trade Name	ULTRA Silver Dressings
Common Name	Wound Dressing
Classification Name	Dressing, Wound, Drug (Product Code: FRO)

3. PREDICATE DEVICE

AFM Ultra Ag Dressings (K093188)

4. DEVICE DESCRIPTION

The ULTRA Silver Dressings are sterile, single-use wound care dressings for use in moist wound management. The dressings are comprised of 4 layers, each performing a specific function; an occlusive synthetic top layer, a polyurethane foam layer, a hot-melt adhesive and a layer of a silver-containing knitted composite fabric.

5. INDICATIONS FOR USE

The ULTRA Silver Dressings are indicated for the management of partial thickness burns, incisions, skin grafts, donor sites, lacerations, abrasions, and Stage I-IV dermal ulcers (vascular, venous, pressure, and diabetic).

6. SUMMARY OF TECHNICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE

The subject of this Special 510(k) is a modification of the AFM Ultra Ag Dressings that was previously cleared on February 17, 2010 under Premarket Notification Number K093188. There are no changes to the fundamental design and technology characteristics. The only change proposed is a modification of the materials in the non-patient contacting layers of the dressing. This modification includes the absorbent foam material, the high MVTR film layer and the hot-melt adhesive that binds the wound contact layer to the foam layer. No modification is being made to the patient contacting component or to the silver component.

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Validation activities to support the use of the ULTRA Silver Dressings consisted of four main elements:

- Biocompatibility Testing
- Validation of Antimicrobial Effectiveness
- Sterility Validation
- Fluid Management Performance

Testing of the ULTRA Silver Dressings has demonstrated that the wound dressing fulfills prospectively defined performance criteria and that the modification system meets user needs.

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

No clinical testing was conducted to support this submission.

9. SUMMARY OF OTHER INFORMATION

No other information is available.

10. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

The similarities in intended use, operational characteristics, and functional technological characteristics between the proposed ULTRA Silver Dressings and the predicate AFM Ultra Ag Dressings lead to a conclusion of substantial equivalence between the proposed and predicate device. A side-by-side comparison of the predicate device and the proposed device is provided in the table below.

Comparison of ULTRA Silver Dressings to Predicate AFM Ultra AG Dressings

Product Characteristics	ULTRA Silver Dressings	AFM Ultra Ag Dressings (K093188)
Intended Use	Management of Partial- to Full Thickness Acute and Chronic Wounds	
Fabric Layer (Wound Contact)	Silver coated polyester/nylon/lycra	Same
Indications	The ULTRA Silver Dressings are indicated for management of partial thickness burns, incisions, skin grafts, donor sites, lacerations, abrasions, and Stage I-IV dermal ulcers (vascular, venous, pressure and diabetic).	Same: The AFM Ultra Ag Dressings are indicated for management of partial thickness burns, incisions, skin grafts, donor sites, lacerations, abrasions, and Stage I-IV dermal ulcers (vascular, venous, pressure and diabetic).
Antimicrobial Components	Silver sodium hydrogen zirconium phosphate	Same
Moisture Management Properties	Yes	Yes
Conformable	Yes	Yes
Multiple Day Use?	Yes	Yes
Thickness	≥ 4.0 mm	≥ 5.5 mm
Porous Fabric Layer	Yes	Yes
Biocompatible	Yes	Yes
Contra-Indications	Known allergy to silver	Same
Packaging	Tyvek/Film Medical Pouch	Same
Sterilization	Gamma Irradiation (25 kGy)	Same